Regenerative Medicine Consortium

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The Regenerative Medicine Consortium brings together leading companies, academic and funding institutions to shape and advance the development of well defined regulatory pathways for stem cell therapies. The entire field moves faster when interested parties share best practices and resources. This group provides a forum for members to discuss amongst themselves or with the FDA issues of importance to the industry. The RMC's mission also includes serving as a technical resource during development of guidelines and standards.

Periodic public webinars and roundtable discussions with the FDA will be announced on this site along with information on how to register and participate.

- Fact Sheet [pdf]

Reference Materials

FDA/NIH

- About pre-IND meetings
- Past presentations
- FDA website links
- Guidance documents
- Advisory committee documents
- Miscellaneous

EMEA and other regulatory agencies

- UK Stem Cell Toolkit
- Committee for Advanced Therapies
    - Reflection Paper on Stem Cell based medicinal products [pdf]

Articles and white papers

- FDA Oversight of Cell Therapy Clinical Trials, Science Translational Medicine, *Science Translational Medicine*, 2012
- Communications with the FDA on the Development Pathway for a Cell-Based Therapy, *Stem Cells Translational Medicine*, 2012
- Translation of Stem Cell Research: Points to Consider in Designing Preclinical Animal Studies, *Stem Cells Translational Medicine*, 2012
- Considerations for Tissue-Engineered and Regenerative Medicine Product Development Prior to Clinical Trials in the United States, *Tissue Engineering*, 10/09 [PDF]
- FDA Regulation of Stem Cell-Based Products, *Science*, 6/26/09

Webinars

- January 21, 2015: CIRM 2.0: We Are Changing the Way We Work
- September 11, 2014: Use of Induced Pluripotent Stem Cells as Screening Tools and Therapeutics
- November 14, 2013: Cell Therapies for Parkinson's Disease from Discovery to Clinic

- June 20, 2013: Reimbursement Strategies Webinar
- April 15, 2013: Clinical Trials: Moving Stem Cell Based Therapies to the Clinic
- September 27, 2012: Immune Response in Stem Cell Therapies
- May 2, 2012: Focus on the Eye
- September 12, 2011: Scaffolding
- May 26, 2011: Imaging Technology for Cellular Therapies
- September 28, 2010: Preclinical Considerations for Stem Cell Therapies
- April 15, 2010: Issues in Product Characterization

Workshops

- September 2013: International Regulatory Considerations on Development Pathways for Cell Therapies [pdf]. Also available via AlphaMed Press.
- October 16, 2012: CIRM/RMC Roundtable Best Practices in Clinical Design for First-in-Human Stem Cell-Based Therapy
- July 10, 2012: NIH & FDA 2nd Public Workshop on Pluripotent Stem Cells in Translation: Early Decisions
- October 24, 2011: CIRM/RMC Roundtable on the Immune Response
- June 29, 2011 8-5pm: FDA CTGTAC Committee Meeting on Treatment of Retinal Disorders
- March 21, 2011: NIH & FDA Public Workshop on Pluripotent Stem Cells in Translation: Early Decisions
- November 2, 2010 8-5:30pm: FDA Public Workshop on Cell and Gene Therapy Clinical Trials in Pediatric Populations

Resources

- ISSCR Stem Cell Resources
- ISSCR - A Closer Look at Stem Cell Treatments
- Alliance for Regenerative Medicine

Contact us

If you have questions concerning the RMC and/or any Webinar or Roundtable content, please contact:

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